

Comment

Teratogens and The Delaney Clause

The Teratology Society, an international scientific organization concerned with the study of the causes and nature of birth defects, recognizes that because of public need, governmental decisions limiting human exposure to potentially teratogenic substances must often be made before definitive proof of an effect in human beings is available. The Society notes, furthermore, that such decisions are hampered by the fact that there are as yet no precise rules by which teratogenic effects in humans may be inferred from experimental results in lower animals, and that, more generally, observations on birth defects cannot be extrapolated uncritically from one species to another.

The Society believes, therefore, that policy decisions concerning possible teratogenic dangers that are mandated by rigid legislative or

*The term "Delaney regulation" is used here in a broad sense to refer to a regulation that mandates as law inferences about human hazards from observations in any lower organism at any dose of exposure. The term derives from the name of the amendment to the Food, Drug, and Cosmetics Act of the U.S.A. concerning the possible carcinogenic potential of food additives. It is emphasized that the resolution of the Society applies only to a "Delaney regulation" for birth defects, not for cancer.

administrative action may be counterproductive. Where these decisions ignore questions of exposure levels and species differences, they may falsely implicate agents that are or would be of social value. Conversely, they may create an illusion of safety, since it is conceivable that human beings may be sensitive to substances found harmless in any set of prescribed testing procedures in lower animals.

The Society is opposed, therefore, to the imposition of a "Delaney-regulation"* for teratogenesis which would decree, in simplistic and arbitrary terms, that any agent found to cause birth defects at any dose in any experimental animal must be classified legally as unsafe and barred from human use. The Society believes it is preferable to have policy decisions on these matters made by regulatory agencies, advised, if not administered, by competent and responsible scientists, who continually review the available evidence, revising decisions in the light of increasing knowledge from the basic and applied sciences.

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